



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 7

11201 Renner Boulevard
Lenexa, Kansas 66219

OCT 31 2016

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Article No.: 7014 1200 0000 6127 0043

C T Corporation System
Trans Ova Genetics, L.C.
Missouri Location
400 E. Court Avenue
Des Moines, Iowa 50309

Re: Trans Ova Genetics, L.C.
Missouri Location

Request for Information

To Whom It May Concern:

Pursuant to Section 308 of the Clean Water Act (CWA), the United States Environmental Protection Agency seeks specific information about the operations of the Trans Ova Genetics, L.C. facility located at: 12425 LIV 224 Chillicothe, Missouri 64601 (the Facility). The information provided in response to the enclosed information request will be used to determine compliance with the CWA and implementing regulations. Section 308 authorizes the EPA to collect information for the purpose of carrying out the objectives of the CWA, including but not limited to, determining the compliance status of an animal feeding operation.

EPA Region 7 inspected the Facility on December 17, 2015. A copy of the inspection report was transmitted to you on July 13, 2016. During this inspection the EPA documented CWA concerns at the Facility. The EPA understands that you may have already taken steps to address some, or all, of the concerns raised during the inspection and documented in the inspection report. The following concerns were noted at the Facility:

1. The holding pond was discharging process wastewater from the overflow southeast through a culvert under the access road and into the unnamed tributary of Coon Creek at the time of the inspection.
2. Cattle in the southeast open lot had direct access to the unnamed tributary of Coon Creek at the time of the inspection.
3. Process wastewater from the Facility's open lots at the south end of the facility flows into an unnamed tributary to Coon Creek.
4. E. Coli counts from the sampling conducted by the EPA inspector exceeded state water quality standards.

The information you provide pursuant to the enclosed information request can help inform the EPA's evaluation of the above identified concerns. Please submit your response within 20 calendar days of receipt of this information request. The enclosure with this correspondence contains instructions followed by the requested information. Please carefully read and follow these instructions. Please note that the EPA retains its authority to pursue appropriate enforcement actions, including penalties for violations discovered as a result of review of your response to this letter, regardless of whether the violations were subsequently corrected. Please send your response to:

Delia Garcia, PhD
Environmental Scientist
WWPD/WENF
US EPA Region 7
11201 Renner Boulevard
Lenexa, Kansas 66219
garcia.delia@epa.gov

Compliance with this information request does not preclude the EPA from assessing penalties or taking any action authorized under the CWA or any other federal law. This information request does not affect the obligation of Trans Ova Genetics, L.C. to comply with the CWA or any other federal, state or local law.

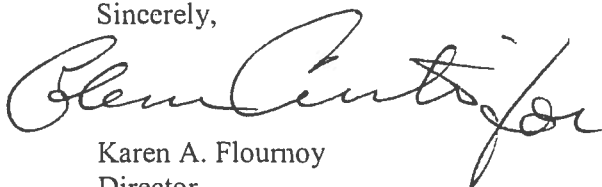
Although EPA requests your assistance to determine compliance, your response is mandatory. Section 309 of the CWA provides civil penalties of up to \$37,500 per day of violation for failing to provide information required under Section 308 of the CWA and criminal penalties for knowingly making a false statement under Section 308.

The information required herein must be submitted notwithstanding any claim you may have concerning confidentiality. However, in accordance with the provisions of 40 C.F.R. § 2.203(b), Trans Ova Genetics, L.C. may assert a business confidentiality claim covering any part of the information set forth in its response. Please review Appendix A of this letter regarding the assertion and substantiation requirements for making a business confidentiality claim.

The Paperwork Reduction Act, 44 U.S.C. Chapter 35, does not apply to the information requested herein.

If you have any questions relating to this matter, contact Clarissa Howley Mills, Office of Regional Counsel, at (913) 551-7743 or mills.clarissa@epa.gov. Thank you for your cooperation in this matter.

Sincerely,



Karen A. Flourney
Director
Water, Wetlands and Pesticides Division

Enclosures

cc: Trans Ova Genetics
2938 380th Street
Sioux Center, Iowa 51250

DeWayne McCauslin
12425 LIV 224
Chillicothe, Missouri 64601

Paul Dickerson (e-copy)
Missouri Department of Natural Resources

Irene Crawford (e-copy)
Missouri Department of natural Resources

Information Request
Trans Ova Genetics, L.C.

For purposes of this information request, the definitions set forth in Section B shall apply and should be considered carefully by you in preparing your responses.

A. INSTRUCTIONS

- 1) Your response must be provided within twenty (20) day of receipt of this information request. The deadline for submittal must be complied with unless a written extension or stay of the deadline for response has been provided by the EPA.
- 2) Perform a thorough and complete search for all information in Trans Ova Genetics L.C.'s possession, custody, and/or control for information that is responsive to this information request. This includes all information that may be in the possession of a third party which Trans Ova Genetics L.C. has the right or ability to obtain upon request or demand. This also includes the obligation to provide written descriptions of responsive information that are based on the personal knowledge of employees of Trans Ova Genetics L.C., including, but not limited to, yourself and/or other employees that worked at or supervised the operations of the referenced Facility.
- 3) Provide the response to each question/request in accordance with the schedule for response and any other instructions specifically set forth for that question/request.
- 4) Provide a separate narrative response to each and every question and subpart of a question set forth in this information request.
- 5) Precede each answer with the number of the question/request to which it corresponds.
- 6) For each and every request, identify all persons consulted in the preparation of the answer.
- 7) Identify the person(s) responding on your behalf to each numbered item in this information request, including their name, title, or position, and organization if other than the Trans Ova Genetics L.C.
- 8) For each and every question in this information request, identify all documents consulted, examined, or referred to in the preparation of the answer or that contain information responsive to the question and provide true and accurate copies of all responsive documents. (If information responsive to an item is available but there are no relevant source documents, you must still provide a narrative response to the request/question.)
- 9) For each document produced in response to the information request, indicate on the document, or in some other reasonable manner, the number of the question/request to which it responds.
- 10) If information responsive to a requested item is not in your possession, identify the person(s) from whom the information may be obtained.

- 11) If information that is not known or available at the time you make your response later becomes known or available to you, you must supplement your response.
- 12) If at any time after you submit your response you find that any part of the information you submitted is incomplete, inaccurate, or misrepresents facts, you must notify the EPA immediately.
- 13) The information requested herein must be provided notwithstanding its possible characterization as confidential information or trade secrets pursuant to 40 C.F.R. § 2.203(b). Appendix A to this letter specifies the assertion and substantiation requirements for business confidentiality claims.
- 14) The EPA encourages you to conserve resources. Suggested methods include use of recycled paper, printing on both sides (duplex printing), and submitting documents electronically (i.e., email or non-rewritable discs) when possible. If hard copy submittals are necessary, please do not submit documents in binders. All documents must be submitted in a legible and readable form.
- 15) Each transmittal of information provided by Trans Ova Genetics L.C. in response to this information request shall be accompanied by a completed and signed Statement of Certification, as provided in Part D, signed by a responsible corporate officer for Trans Ova Genetics L.C.
- 16) A request for an extension to the time limit for responding must be in writing and sent within five (5) calendar days of receipt of this information request. Please address the request to the EPA contact identified in the cover letter.

B. DEFINITIONS:

All terms used in the foregoing letter and in this information request will have their ordinary meaning unless such terms are defined in the Clean Water Act or other Clean Water Act implementing regulations. Definitional clarification is specified below.

- 1) "You" or "Your" means Trans Ova Genetics, L.C. including but not limited to its predecessors, successors, subsidiaries, parent companies, affiliates, d/b/a, divisions, branches, offices, franchises, facilities, committees, trusts, partnerships and joint ventures in which it has any interest; all entities for which it is acting as an agent or contractor; and its past or present officers, directors, trustees, managers, employees, agents, consultants, contractors, attorneys, representatives and any other persons acting on its behalf.
- 2) Pursuant to Section 502(5) of the CWA, 33 U.S.C. § 1362(5), "person" as used herein, in the plural as well as the singular, includes an individual, corporation, partnership, association, state, municipality, commission, or political subdivision of a state, or any interstate body and any officer, agent or employee thereof.
- 3) "Employee" shall mean any common law employee, contractor, sub-contractor or independent contractor working for Trans Ova Genetics, L.C. in any capacity.
- 4) "And" as well as "or" shall be construed either conjunctively or disjunctively as necessary to bring within the scope of this information request all information which might otherwise be construed to be outside its scope.
- 5) "Furnish," "describe," "identify" or "indicate" means turning over to the EPA duplicate copies of the requested information in the possession, custody or control of Trans Ova Genetics, L.C. Where specific information has not been memorialized in any document but is nonetheless responsive to a request, you must respond to the request with a written response. If such requested information is not in your possession, custody or control then indicate where such information or documents may be obtained.
- 6) "Document" or "documents" means any written, recorded or graphic material of any kind, whether prepared by you or by any other person that is in your possession, custody or control. The term includes but is not limited to: contracts, agreements, certificates, permits, letters, facsimiles, telegrams, interoffice communications, email messages and attachments, memoranda, notes, books, files, records, reports, evaluations, proposals, analyses, notebooks, surveys, lists, outlines, drafts, schedules, pamphlets, newsletters, flyers, charts, logs, tabulations, compilations, telephone books or messages, visitor books, calendar or diary entries, desk or appointment calendars, day planners, business cards, minutes or notations or records of meetings or conferences, notes or memos or other records of telephone or other conversations or communications, ledgers, bills, invoices, purchase orders, shipping orders, statements of receipt or shipment, work requests, work orders, scribbles, marginalia, drawings, depictions, maps, testing data, receipts, photographs, diagrams, illustrations, plans, blueprints, schematics, photostats, microfilm, microfiche, audio and video tape or disc recordings and computer printouts. It also includes electronically stored data from which information can be obtained either directly or by translation through detection devices or readers, including but not limited to information stored on a computer hard drive, magnetic tape, cassette, disk, CD, Internet Service Provider or network. Any such document is to be produced in usable form, along with instructions for reading such data. As indicated in the preceding section, the term

"document" includes the original (or a copy thereof if the original is not available) and all copies that differ in any respect from the original, or that bear any handwriting, notation, marking or information not on the original.

C. INFORMATION REQUEST:

Information requested pursuant to Section 308 of the CWA, 33 U.S.C. § 1318:

- 1) Identify the person(s) responding to this request. Include names, titles, telephone numbers and email addresses.
- 2) Identify the person(s) consulted in preparing the responses to this request. Include names, titles, telephone numbers and email addresses.
- 3) Identify all documentation consulted, examined or referred to in preparing the answers to this request and provide copies of all such documents.
- 4) From December 1, 2014 to present, provide the exact inventory of animals, including beef cattle, dairy, swine, turkeys, chickens and sheep, at the Facility.
- 5) Describe and document through as-built plans, diagrams and/or photographs the runoff controls that have been constructed to ensure that any release of process wastewater from the holding pond will not discharge into the unnamed tributary of Coon Creek.
- 6) Describe and provide documentation relating to the actions you have taken to permanently ensure that the livestock located in the southeast open pen do not have direct access to the unnamed tributary of Coon Creek.
- 7) Describe the best management practices implemented at the Facility to ensure that any release of process wastewater from the Facility is not discharged into the unnamed tributary of Coon Creek.

D. CERTIFICATION OF RESPONSES:

STATEMENT OF CERTIFICATION

Trans Ova Genetics, L.C. is submitting the enclosed documents in response to the EPA's request for information to determine whether the Trans Ova Genetics, L.C. is in compliance with the Clean Water Act and implementing regulations.

I am a responsible officer of _____.

I certify under penalty of law that I have personally examined and am familiar with, the statements and information submitted in the enclosed documents, including all attachments. Based on my inquiry of those individuals with primary responsibility for obtaining the information, I certify that the statements and information are to the best of my knowledge and belief true, correct, accurate, and complete. I am aware that there are significant penalties for submitting false statements and information, or omitting required statements and information, including the possibility of fine or imprisonment.

Date: _____

Signature: _____

Title _____

Appendix A

Confidential Business Information (CBI) Assertion and Substantiation Requirements

A. Assertion Requirements

You may assert a business confidentiality claim covering all or part of the information requested in the attached letter, as provided in 40 C.F.R. § 2.203(b). To make a confidentiality claim, submit the requested information and indicate that you are making a claim of confidentiality. Any document over which you make a claim of confidentiality should be marked by placing on or attaching to the information, at the time it is submitted to United States Environmental Protection Agency (EPA), a cover sheet, stamped or typed legend, or other suitable form of notice employing language such as "trade secret" or "proprietary" or "company confidential" and a date, if any, when the information should no longer be treated as confidential. Information covered by such a claim will be disclosed by the EPA only to the extent permitted and by means of the procedures set forth by 40 C.F.R. Part 2. Allegedly confidential portions of otherwise non-confidential documents should be clearly identified. EPA will construe the failure to furnish a confidentiality claim with your response to the attached letter as a waiver of that claim and the information may be made available to the public without further notice to you.

Please segregate personnel, medical and similar files from your responses and include that information on separate sheet(s) marked as "Personal Privacy Information" given that disclosure of such information to the general public may constitute an invasion of privacy.

B. Substantiation Requirements

All confidentiality claims are subject to EPA verification and must be made in accordance with 40 C.F.R. § 2.208 which provides in part that you satisfactorily show that you have taken reasonable measures to protect the confidentiality of the information and that you intend to continue to do so; and that the information is not and has not been reasonably obtainable by legitimate means without your consent.

Pursuant to 40 C.F.R. Part 2, Subpart B, EPA may at any time send you a letter asking you to substantiate fully your CBI claim. You must provide EPA with a response within the number of days set forth in the EPA request letter. Failure to submit your comments within that time will be regarded as a waiver of your confidentiality claim or claims and EPA may release the information. EPA will ask you to specify which portions of the information you consider confidential. **You must be specific by page, paragraph and sentence when identifying the information subject to your claim.** Any information not specifically identified as subject to a confidentiality claim may be disclosed to the requestor without further notice to you. For each item or class of information that you identify as being subject to CBI, EPA will ask you to answer the following questions, giving as much detail as possible:

- I. For what period of time do you request that the information be maintained as confidential, e.g., until a certain date, until the occurrence of a specified event or permanently? If the occurrence of a specific event will eliminate the need for confidentiality, please specify that event.
- II. Information submitted to EPA becomes stale over time. Why should the information you claim as confidential be protected for the time period specified in your answer to question

#1?

- III. What measures have you taken to protect the information claimed as confidential? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose the information further? If so, why should the information still be considered confidential?
- IV. Is the information contained in any publicly available material such as the Internet, publicly available databases, promotional publications, annual reports or articles? Is there any means by which a member of the public could obtain access to the information? Is the information of a kind that you would customarily not release to the public?
- V. Has any governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.
- VI. For each category of information claimed as confidential, explain with specificity why release of the information is likely to cause substantial harm to your competitive position. Explain the specific nature of those harmful effects, why they should be viewed as substantial and the causal relationship between disclosure and such harmful effects. How could your competitors make use of this information to your detriment?
- VII. Do you assert that the information is submitted on a voluntary or a mandatory basis? Please explain the reason for your assertion. If you assert that the information is voluntarily submitted information, explain whether and why disclosure of the information would tend to lessen the availability to EPA of similar information in the future.
- VIII. Any other issue you deem relevant.

If you receive a request for a substantiation letter from the EPA, you bear the burden of substantiating your confidentiality claim. Conclusory allegations will be given little or no weight in the determination. In substantiating your CBI claim(s), EPA will require you to bracket all text so claimed and mark it "CBI." Information so designated will be disclosed by EPA only to the extent allowed by, and by means of the procedures set forth in, 40 C.F.R. Part 2, Subpart B. If you fail to claim the information as confidential, it may be made available to the public without further notice to you.